

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

_____	X	
PRO PUBLICA, INC.,	:	
	:	
	:	
Plaintiff,	:	
	:	<b><u>COMPLAINT</u></b>
- against –	:	
	:	
UNITED STATES FOOD AND DRUG	:	CIVIL ACTION NO.: 19-CV-5178
ADMINISTRATION,	:	
	:	
Defendant.	:	
	:	
_____	X	

Plaintiff PRO PUBLICA, INC., (“ProPublica”), by its undersigned attorney, alleges for its Complaint:

1. This is an action under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, to obtain an order for the production of agency records from Defendant United States Food and Drug Administration (“FDA”), in response to a FOIA request properly made by Plaintiff.
2. The records sought here are contracting documents that account for tens of millions of dollars of federal government spending on consulting services covering a wide array of FDA functions.

**PARTIES**

3. Plaintiff ProPublica is a non-partisan newsroom based in New York. It is a Delaware non-profit corporation, and is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code. As an independent news organization dedicated to producing investigative journalism in the public interest, it has been honored with numerous awards, including five Pulitzer Prizes. ProPublica publishes its reporting through its website,

www.propublica.org, and in partnership with more than 180 news organizations across the country, including The New York Times, The Washington Post, Politico, NPR News, The Miami Herald, The New Yorker, The Boston Globe, The Los Angeles Times, and Frontline. ProPublica is headquartered in this judicial district at 155 Avenue of the Americas, 13th Floor, New York, New York 10013.

4. Defendant FDA is an agency of the federal government that has possession and control of the records that Plaintiff seeks. It is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20993-002.

### **JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

6. Venue is premised on the place of business of Plaintiff and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

7. Plaintiff has exhausted all administrative remedies available. An agency must make and communicate its determination whether to comply with a request under FOIA within 20 business days of receiving the request, 5 U.S.C. § 552(a)(6)(A)(i), or within 30 business days if the agency determines that unusual circumstances apply. 5 U.S.C. § 552(a)(6)(B)(i)-(iii). FDA has failed to make initial determinations with respect to Plaintiff's request within the timeframe set by FOIA, and Plaintiff is therefore deemed to have exhausted all administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C).

### **FACTS**

8. On December 31, 2018, ProPublica and its reporter Ian MacDougall submitted a series of FOIA requests related to 48 separate FDA contracts.

9. The FDA acknowledged submission of the requests that same day.
10. On January 30, 2019, at the request of a Senior Freedom of Information Specialist at the FDA, ProPublica amended its requests into a single request seeking documents related to those contracts (the “Request”).
11. As amended, the Request sought:
  1. Any contracts (including any amendments, modifications, or extensions) – as well as and Statement or Scope of Work documents – for the FDA contracts with McKinsey & Company listed below.
  2. Any bid documents submitted by McKinsey in its successful bid to secure the below-listed contracts (including proposal documents submitted for amendments, modifications, or extensions).<sup>1</sup>
12. The Request further stated that bid documents “are subject to FOIA, pursuant to 41 U.S.C. § 4702(c) and 21 C.F.R. § 20.109(b).”
13. The Request concerned the following 48 FDA contracts:
  - Contract ID: HHSF22317002; Reference IDV: HHSF223201610024B; Signed March 14, 2017
  - Contract ID: HHSF22317003; Reference IDV: HHSF223201610024B; Signed March 28, 2017
  - Contract ID: HHSF22317004; Reference IDV: HHSF223201610024B; Signed June 20, 2017
  - Contract ID: HHSF22317005; Reference IDV: HHSF223201610024B; Signed August 16, 2017
  - Contract ID: HHSF22317006; Reference IDV: HHSF223201610024B; Signed August 17, 2017
  - Contract ID: HHSF223201700022B; Reference IDV: GS10F0118S; Signed September 26, 2017
  - Contract ID: HHSF22317001; Reference IDV: HHSF223201700022B; Signed September 28, 2017
  - Contract ID: HHSF22318001; Reference IDV: HHSF223201700022B; Signed December 5, 2017

---

<sup>1</sup> The Request also initially sought “non-draft reports or slide decks/PowerPoints provided to the FDA by McKinsey pursuant to the below-listed contracts (including pursuant to amendments, modifications, or extensions), including interim reports or slide decks, pursuant to 21 C.F.R. § 20.109(a).” Plaintiff does not seek this category of documents in this action.

- Contract ID: HHSF22318002; Reference IDV: HHSF223201700022B; Signed December 12, 2017
- Contract ID: HHSF22318003; Reference IDV: HHSF223201700022B; Signed January 4, 2018
- Contract ID: HHSF22318004; Reference IDV: HHSF223201700022B; Signed January 12, 2018
- Contract ID: HHSF22318005; Reference IDV: HHSF223201700022B; Signed January 25, 2018
- Contract ID: HHSF22318006; Reference IDV: HHSF223201700022B; Signed March 26, 2018
- Contract ID: HHSF22318007; Reference IDV: HHSF223201700022B; Signed May 14, 2018
- Contract ID: HHSF22318008; Reference IDV: HHSF223201700022B; Signed June 12, 2018
- Contract ID: HHSF22318010; Reference IDV: HHSF223201700022B; Signed July 31, 2018
- Contract ID: HHSF22318011; Reference IDV: HHSF223201700022B; Signed August 1, 2018
- Contract ID: HHSF22318013; Reference IDV: HHSF223201700022B; Signed August 2, 2018
- Contract ID: HHSF22318012; Reference IDV: HHSF223201700022B; Signed August 14, 2018
- Contract ID: HHSF22318014; Reference IDV: HHSF223201700022B; Signed August 22, 2018
- Contract ID: HHSF22318009; Reference IDV: HHSF223201700022B; Signed August 23, 2018
- Contract ID: HHSF22318015; Reference IDV: HHSF223201700022B; Signed September 12, 2018
- Contract ID: HHSF22318016; Reference IDV: HHSF223201700022B; Signed September 25, 2018
- Contract ID: HHSF223200830274G; Reference IDV: GS10F0118S; Signed January 30, 2008
- Contract ID: HHSF223201010014B; Reference IDV: GS10F0118S; Signed April 15, 2010
- Contract ID: HHSF22301002; Reference IDV: HHSF223201010014B; Signed April 22, 2010
- Contract ID: HHSF22301005; Reference IDV: HHSF223201010014B; Signed April 29, 2010
- Contract ID: HHSF22301006; Reference IDV: HHSF223201010014B; Signed April 30, 2010
- Contract ID: HHSF22301008; Reference IDV: HHSF223201010014B; Signed August 2, 2010

- Contract ID: HHSF22301009; Reference IDV: HHSF223201010014B; Signed September 9, 2010
- Contract ID: HHSF22301010; Reference IDV: HHSF223201010014B; Signed September 13, 2010
- Contract ID: HHSF22311002; Reference IDV: HHSF223201010014B; Signed January 14, 2011
- Contract ID: HHSF22311005; Reference IDV: HHSF223201010014B; Signed July 21, 2011
- Contract ID: HHSF22311009; Reference IDV: HHSF223201010014B; Signed September 12, 2011
- Contract ID: HHSF22312002; Reference IDV: HHSF223201010014B; Signed November 17, 2011
- Contract ID: HHSF22312005; Reference IDV: HHSF223201010014B; Signed June 28, 2012
- Contract ID: HHSF22312006; Reference IDV: HHSF223201010014B; Signed July 3, 2012
- Contract ID: HHSF22312007; Reference IDV: HHSF223201010014B; Signed July 13, 2012
- Contract ID: HHSF22312011; Reference IDV: HHSF223201010014B; Signed September 5, 2012
- Contract ID: HHSF22313003; Reference IDV: HHSF223201010014B; Signed July 27, 2013
- Contract ID: HHSF22314003; Reference IDV: HHSF223201010014B; Signed April 30, 2014
- Contract ID: HHSF22314001; Reference IDV: HHSF223201010014B; Signed June 19, 2014
- Contract ID: HHSF22315001; Reference IDV: HHSF223201010014B; Signed February 3, 2015
- Contract ID: HHSF22315003; Reference IDV: HHSF223201010014B; Signed February 25, 2015
- Contract ID: HHSF22315006; Reference IDV: HHSF223201010014B; Signed July 22, 2015
- Contract ID: HHSF22316001; Reference IDV: HHSF223201610024B; Signed September 16, 2016
- Contract ID: HHSF223201610024B; Reference IDV: GS10F0118S; Signed September 16, 2016
- Contract ID: HHSF22317001; Reference IDV: HHSF223201610024B; Signed November 8, 2016

14. No final determination has been issued, and no documents have been produced.

15. FDA has failed to issue a response to the request within 20 business days as required under FOIA. *See* 5 U.S.C. § 552(a)(6).

### **COUNT I**

16. Plaintiff repeats, realleges, and reincorporates the allegations in the foregoing paragraphs as though fully set forth herein.

17. Defendant FDA is subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any materials as to which it is claiming an exemption.

18. FDA has failed to act on Plaintiff's request within 20 business days as required by FOIA. *See* 5 U.S.C. § 552(a)(6)(A)(i). Accordingly, Plaintiff is deemed to have exhausted its administrative remedies under FOIA.

19. FDA has no lawful basis for declining to release the records requested by Plaintiff under FOIA.

20. Accordingly, Plaintiff is entitled to an order compelling FDA to produce records responsive to its FOIA request.

### **REQUESTS FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that this Court:

21. Declare that the documents sought by its FOIA request, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

22. Order FDA to provide the requested documents to Plaintiff within 20 business days of the Court's order;

23. Award Plaintiff the costs of this proceeding, including reasonable attorneys' fees, as expressly permitted by FOIA; and

24. Grant Plaintiff such other and further relief as this Court deems just and proper.

Dated: New York, New York  
June 3, 2019

/s/  
Jeremy A. Kutner, Esq.  
Deputy General Counsel  
ProPublica  
155 Avenue of the Americas, 13th Floor  
New York, NY 10013  
Phone: (917) 512-0218  
Fax: (212) 785-2634  
E-mail: [jeremy.kutner@propublica.org](mailto:jeremy.kutner@propublica.org)  
*Counsel for Plaintiff*